REMARKS

Claims 22, 23, 28-49 and 67-84 have been withdrawn from consideration. Claims 1-16, 21 and 85 are pending in the application.

Applicants thank Examiner Ton and SPE Paras ("the Examiners") for their time and helpful comments in the interview with the Applicants' representatives on November 14, 2007. As a follow up to this interview, Applicants submit the following Remarks.

During the interview, Applicants' representatives and the Examiners discussed the utility of viable embryos as claimed in the pending application. Examiner Ton suggested that the only potential uses of such viable embryos were to create cloned animals or embryonic stem cells. Therefore, to maintain this utility, Examiner Ton continues to read the necessity of creating cloned animals or embryonic stem cells into the pending claim set. By requiring these specific uses, despite the fact that they are not required by, or elements of, any pending claim, Examiner Ton continues to maintain enablement rejections for this reason.

During the interview, Applicants' representatives stressed that there are many uses of viable embryos produced by the claimed methods beyond those of creating cloned animals or embryonic stem cells and that Examiner Ton's position on utility was scientifically unfounded and unsupportable. Particularly, Applicants' representatives highlighted the use of the claimed viable embryos as a valuable research tool to, *inter alia*, further the goals of creating cloned animals, embryonic stem cells or to perform other research aimed at elucidating the cellular mechanisms of sexual reproduction.

To demonstrate that those of ordinary skill in the art recognize the importance of viable embryos in their on-going research endeavors, Applicants respectfully submit recent articles (see attached Supplemental Information Disclosure Statement) discussing the creation of induced pluripotent stem cells (iPS) from human skin cells and the reactions of those of ordinary skill in the art. Specifically, these articles include Yu *et al.*, Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells (November 20, 2007) www.sciencexpress.org (10.1126/science.1151526) and Takahashi *et al.*, Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors, 31 Cell 861-872 (November 30, 2007). Applicants make these articles of record in the present application to demonstrate that (i) as with the embryos and methodology described in the pending application, the utility of the created iPS is still for research purposes (as continually emphasized by Applicants) and (ii) both the embryos described in the

pending application as well as the iPS recently disclosed have enormous utility in furthering important research goals.

As stated, the articles submitted on the attached Supplemental Information Disclosure Statement discuss the recent announcements of Dr. James Thomson from the University of Wisconsin at Madison and Dr. Shinya Yamanaka from Kyoto University regarding their independent production of iPS from human skin cells. Despite the production of iPS, which do not require the use of embryos, both authors highlight the continued importance of research to produce human embryonic stem cells (hES). For instance, the Yu et al., article states that, "[s]imilar to human ES cells, human iPS cells should prove useful for studying the development and function of human tissues, for discovering and testing new drugs, and for transplantation medicine." Yu *et al., supra.* The Takahashi et al. article states, "[h]uman iPS cells ... are not identical to hES cells: DNA microarray analyses detected differences between the two pluripotent stem cell lines. Further studies are essential to determine whether human iPS cells can replace hES cells in medical applications." Takahashi *et al., supra.*

According to those of skill in the art, such as Deepak Srivastava, Director of the Gladstone Institute of Cardiovascular Disease "[Dr. Thomson and Dr. Yamanaka's] work is monumental in its importance to the field of stem cell science and its potential impact on our ability to accelerate the benefits of this technology to the bedside." Stem Cell Breakthrough Uses Human Skin Not Embryos (November 20, 2007) Physorg.com (www.physorg.com/news114773905).

According to Dr. Yamanaka, "[t]hese cells should be extremely useful in understanding disease mechanisms and screening effective and safe drugs." *Id.* Dr. Yamanaka added, "[w]e are still a long way from finding cures or therapies from stem cells and we don't know what processes will be effective." *Id.*

Despite the lack of a use that goes beyond research purposes at this point, Rudolf Jaenisch, a stem cell scientist at the White Institute in Cambridge, Mass stated "It's a huge deal." Malcolm Ritter, Stem Cell Breakthrough Uses No Embryos (November 20, 2007) www.livescience.com (www.livescience.com/health/071120-ap-stem-cells). Dr. Jaenisch also cautioned however, that cloning methodologies to produce embryonic stem cells should still be pursued because "[c]loning embryos to produce stem cells remains too valuable as a research tool." *Id.* As explained by Applicants' representatives to

Examiners during the November 14, 2007 interview, this valuable research tool cannot be pursued without the prerequisite methodology to produce viable embryos as defined, for example, in the pending application.

These publications, passages, and quotations from those of ordinary skill in the art demonstrate the importance of created embryos and embryonic stem cells for research purposes.

To demonstrate to the Examiner that written support for other uses of viable embryos beyond the complete production of cloned animals and embryonic stem cells appears in the application as-filed, Applicants point the Examiner's attention to the following passages from the specification (note that underlined emphasis is added):

> [0007] Theoretically, somatic cell nuclear transfer (SCNT) has the potential to produce limitless identical offspring; however, genetic chimerism, fetal and neonatal death rates ..., shortened telomeres ..., and inconsistent success rates preclude its immediate usefulness. ... These concerns notwithstanding, the contradictions and paradoxes raised by SCNT have stimulated new studies on the molecular regulation of mammalian cloning by SCNT.
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> [0011] The present invention is directed to various methodologies to make NT a practical procedure for animals, and specifically primates. Furthermore, the methods and molecular components provided by the present invention provide a practical means for producing embryos with desired characteristics. In one embodiment, the methodology of the present invention comprises ..., transferring the embryo to the oviducts of a female, and producing a cloned animal.
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> [0032] For the purposes of the present invention, the term "embryo" or "embryonic" as used herein includes a developing cell mass that has not implanted into the uterine membrane of a maternal host. Hence, the term "embryo" as used herein can refer to a fertilized oocyte, a cybrid, a pre-blastocyst stage developing cell mass, and/or any other developing cell mass that is at a stage of development prior to implantation into the uterine membrane of a maternal host. ....

[0033] An embryo can represent multiple stages of cell development. ....

[0034] The term "fetus" as used herein refers to a developing cell mass that has implanted into the uterine membrane of a maternal host. ....

[0044] ... The methodologies provided by the present invention are capable of evaluating mechanisms for potential nuclear transfer failures related to first mitotic errors, previously elusive of efficient detection.

[0053] The present invention has several important benefits for the biomedical research community. By expanding animal and specifically primate reproduction to include transgenic and SCNT capabilities, the utility of this model for essential and urgent pre-clinical investigations may be greatly enhanced. SCNT may find extraordinary applications, were it developed as a reliable, routine approach for propagating invaluable primate models. .... Furthermore, the combination of these approaches might even result in reliable and efficient applications for propagating invaluable transgenic primates as research models. Finally, the promise of safe and effective gene therapy protocols cannot be fully realized until an appropriate system for investigation is found to fill the gap between transgenic mice and seriously ill patients. .... Thus, the present invention may have clinical and investigative applications which include, but are not limited to, cell therapy (neural, brain, and spinal stem cell applications, liver stem cell applications, pancreas stem cell applications, cardiac stem cell applications, renal stem cell applications, blood stem cell applications, retinal stem cell applications, diabetes-stem cell applications, orthopedics-stem cell applications, identical primate models for research, drug discovery, embryonic stem cells for drug discovery), pharmaceutical and medical devices (including animal models of disease for drug discovery and testing, pharmacological target identification, drug discovery, drug efficacy testing, biocompatibility of medical devices), agriculture, rare and endangered species, and toxicology evaluation.

Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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